State of Utah
Administrative Rule Analysis

NOTICE OF CHANGE IN PROPOSED RULE

The agency identified below in box 1 provides notice of proposed rule change pursuant to *Utah Code* Sections 63-46a-4. Please address questions regarding information on this notice to the agency. The full text of all rule filings is published in the *Utah State Bulletin* unless excluded because of space constraints. The full text of all rule filings my also be inspected at the Division of Administrative Rules.

DAR file no:		Date filed:	
Utah Admin. Code ref. (R no.):	R156-17b	Time filed:	
Changed to Admin. Code Ref. (R no.):			

1.	Agency:	Commerce/Division of Occupational and Professional Licensing		
	Room no.:			
	Building:	Heber M. Wells Building		
	Street address 1:	160 East 300 South		
	Street address 2:			
	City, state, zip:	Salt Lake City UT 84111-2316		
	Mailing address 1:	PO Box 146741		
	Mailing address 2:			
	City, state, zip:	Salt Lake City UT 84114-6741		
	Contact person(s):			
	Name:	**Phone:**	**Fax:**	**E-mail:**
	Diana Baker	801-530-6179	801-530-6511	dbaker@utah.gov

(Interested persons may inspect this administrative rule at the above address or at DAR between 8:00 a.m. and 5:00 p.m. on business days.)

2.	**Title of rule or section** (catchline)**:**	
	Pharmacy Practice Act Rules	
3.	**Type of notice:** Change in Proposed Rule	
	Changes original proposed rule file no.:	27529
4.	**Purpose of the rule or reason for the change:**	
	Following a public rule hearing and further review by the Division and the Pharmacy Board, additional amendments are being proposed.	
5.	**This change is a response to comments from the Administrative Rules Review Committee.**	
	Yes ___; No XX	
6.	**Summary of the rule change:**	

	Throughout the rule, various grammatical and spelling changes have been made. Section 102-Definitions: Deleted the definitions for "Internet pharmacy" and "VIPPS" and renumbered the remaining paragraphs. Also added to the definition of "USP-NF" that it includes Supplement 1, dated April 1, 2005. Section 301-Pharmacist-in-Charge Requirements: In paragraph (1) regarding Class A pharmacies, deleted reference to Internet pharmacies. In paragraph (2) regarding Class B pharmacies, added that methadone clinics are included in this classification. In paragraph (4) regarding Class D pharmacies, deleted reference to Internet pharmacies. Section 304-Education Requirements: In paragraph (3)(c)(i) deleted language regarding dates that have passed regarding pharmacy technician eligibility and training. In paragraph (4)(c), added an option to use an additional certification body. Section 402-Administrative Penalties: Deleted that failing to wear a name tag was cause for an administrative penalty and renumbered remaining paragraphs. Section 612-Operating Standards/Prescriptions - Updated paragraph (13) by adding "legend drugs" for limited transfer of prescriptions with exceptions. Section 616-Class D pharmacy/Out of State Mail Order Pharmacies: updated title of section for clarity.
7.	**Aggregate anticipated cost or savings to:**
	A) State budget:
	The Division does not anticipate any additional costs or savings beyond those previously identified in the original rule filing as a result of these additional proposed amendments.
	B) Local government:
	This proposed rule does not affect local governments. The rule only affects licensed pharmacists, pharmacy interns, pharmacy technicians and pharmacies. Therefore, there is no anticipated costs or savings to local governments.
	C) Other persons:
	The Division does not anticipate any additional costs or savings beyond those previously identified in the original rule filing and the subsequent change in proposed rule filing as a result of these additional proposed amendments.
8.	**Compliance costs for affected persons** ("person" means any individual, partnership, corporation, association, governmental entity, or public or private organization or any character other than an agency)**:**
	The Division does not anticipate any additional costs or savings beyond those previously identified in the original rule filing and the subsequent change in proposed rule filing as a result of these additional proposed amendments.
9.	**Comments by the department head on the fiscal impact the rule may have on businesses:**
	No fiscal impact to businesses is expected as a result of this change in proposed rules beyond the original rule filing. Russell C. Skousen, Executive Director
10.	**This rule change is authorized or mandated by state law, and implements or interprets the following state and federal laws.State code or constitution citations** (required)**:**
	Sections 58-17b-101and 58-37-1and Subsections 58-17b-601(1), 58-1-106(1)(a) and 58-1-202(1)(a)
11.	**This rule adds, updates, or otherwise changes the following titles of materials incorporated by references** (a copy of materials incorporated by reference must be submitted to DAR; if none, leave blank)**:**
	Deletes the VIPPS (Verified Internet Pharmacy Practice Sites) Criteria Document, dated September 14, 2004, as established by NABP (National Association of Board of Pharmacy) Adds Supplement 1, dated April 1, 2005, to the USP 28-NF 23.
12.	**The public may submit written or oral comments to the agency identified in box 1.** (The public may also request a hearing by submitting a written request to the agency. The agency is required to hold a hearing if it receives requests from ten interested persons or from an association having not fewer than ten members. Additionally, the request must be received by the agency not more than 15 days after the publication of this rule in the *Utah State Bulletin*. See Section 63-46a-5 and Rule R15-1 for more information.)

	A) Comments will be accepted until 5:00 p.m. on (mm/dd/yyyy)**:**		05/16/2005
	B) A public hearing (optional) will be held:		
	on (mm/dd/yyyy)**:**	**at** (time)**:**	**At** (place)**:**
13.	**This rule change may become effective on** (mm/dd/yyyy)**:**		05/17/2005
	NOTE: The date above is the date on which this rule MAY become effective. It is *NOT* the effective date. After the date designated in Box 12(A) above, the agency *must* submit a Notice of Effective Date to the Division of Administrative Rules to make this rule effective. Failure to submit a Notice of Effective Date will result in this rule lapsing and will require the agency to start the rulemaking process over.		
14.	**Indexing information -- keywords** (maximum of four, in lower case, except for acronyms (e.g., "NASA") or proper nouns (e.g., "Medicaid")**:**		
	pharmacists	licensing	
	pharmacies		
15.	**Attach an RTF document containing the text of this rule change** (filename)**:**		R156-17b.cpr2

To the agency: Information requested on this form is required by Sections 63-46a-4, 5, 6, and 10. Incomplete forms will be returned to the agency for completion, possibly delaying publication in the *Utah State Bulletin*, and delaying the first possible effective date.

AGENCY AUTHORIZATION

Agency head or designee, and title:	J. Craig Jackson, Director	**Date** (mm/dd/yyyy)**:**	03/31/2005

ChangeInProposedRule.doc 9/26/2003

R156. Commerce, Occupational and Professional Licensing.
R156-17b. Pharmacy Practice Act Rules.
R156-17b-102. Definitions.

In addition to the definitions in Title 58, Chapters 1 and 17b, as used in Title 58, Chapters 1 and 17b or these rules:

(1) "ACPE" means the American Council on Pharmaceutical Education or Accreditation Council for Pharmacy Education.

(2) "Drugs", as used in these rules, means drugs or devices.

(3) "Dispense", as defined in Subsection 58-17b-102(23), does not include transferring medications for a patient from a legally dispensed prescription for that particular patient into a daily or weekly drug container to facilitate the patient taking the correct medication.

(4) "Drug therapy management" means the review of a drug therapy regimen of a patient by one or more pharmacists for the

purpose of evaluating and rendering advice to one or more practitioners regarding adjustment of the regimen.

(5) "High-risk, medium-risk, and low-risk drugs" refers to the risk to a patient's health from compounding sterile preparations, as referred to in USP-NF Chapter 797, for details of determining risk level.

(6) "Hospice facility pharmacy" means a pharmacy that supplies drugs to patients in a licensed healthcare facility for terminal patients.

(7) "Hospital clinic pharmacy" means a pharmacy that is located in an outpatient treatment area where a pharmacist or pharmacy intern is compounding, admixing, or dispensing prescription drugs, and where:

(a) prescription drugs or devices are under the control of the pharmacist, or the facility for administration to patients of that facility;

(b) prescription drugs or devices are dispensed by the pharmacist or pharmacy intern; or

(c) prescription drugs are administered in accordance with the order of a practitioner by an employee or agent of the facility.[

~~(8) "Internet pharmacy" means a pharmacy licensed as either a Class A or Class D pharmacy that meets the VIPPS criteria as established by NABP and provides the following services via an Internet website, regardless of the quantum of the services:~~

~~(a) receives and fills valid prescription orders from a prescriber; or~~

~~(b) receives and fills refill requests from a patient who has a valid prescription order.~~]

([~~9~~]8) "Legend drug" means any drug or device that has been determined to be unsafe for self-medication or any drug or device that bears or is required to bear the legend:

(a) "Caution: federal law prohibits dispensing without prescription";

(b) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or

(c) "Rx only".

([~~10~~]9) "Maintenance medications" means medications the patient takes on an ongoing basis.

([~~11~~]10) "MPJE" means the Multistate Jurisprudence Examination.

([~~12~~]11) "NABP" means the National Association of Boards of Pharmacy.

([~~13~~]12) "NAPLEX" means North American Pharmacy Licensing Examination.

([~~14~~]13) "Parenteral" means a method of drug delivery injected into body tissues but not via the gastrointestinal tract.

([~~15~~]14) "PTCB" means the Pharmacy Technician Certification Board.

([~~16~~]15) "Qualified continuing education", as used in these rules, means continuing education that meets the standards set forth in Section R156-17b-309.

([~~17~~]16) "Sterile products preparation facility" means any facility, or portion of the facility, that compounds sterile products using aseptic technique.

([~~18~~]17) "Unauthorized personnel" means any person who is not participating in the operational processes of the pharmacy who in some way would interrupt the natural flow of pharmaceutical care.

([~~19~~]18) "Unit dose" means the ordered amount of a drug in a dosage form prepared for a one-time administration to an individual and indicates the name, strength, lot number and expiration date for the drug.

([~~20~~]19) "Unprofessional conduct", as defined in Title 58, Chapters 1 and 17b, is further defined, in accordance with Subsection 58-1-203(1)(e), in Section R156-17b-502.

([~~21~~]20) "USP-NF" means the United States Pharmacopeia-National Formulary (USP 28-NF 23), 2004 edition, which is official from January 1, 2005 through Supplement 1, dated April 1, 2005, which is hereby adopted and incorporated by reference.[~~(22) "VIPPS" means Verified Internet Pharmacy Practice Sites. Pharmacies displaying the VIPPS seal have demonstrated to NABP their compliance with VIPPS criteria including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists. The VIPPS Criteria document, dated September 14, 2004, as established by NABP is adopted and incorporated by reference.~~]

R156-17b-301. Pharmacy Licensure Classifications - Pharmacist-in-Charge Requirements.

In accordance with Subsection 58-17b-302(4), the classification of pharmacies holding licenses are clarified as:

(1) Class A pharmacy includes all retail operations[~~, including pharmacies~~] located in Utah [~~that fill from Internet prescriptions,~~] and requires a pharmacist-in-charge.

(2) Class B pharmacy includes an institutional pharmacy that provides services to a target population unique to the needs of the healthcare services required by the patient. All Class B pharmacies require a pharmacist-in-charge except for pharmaceutical administration facilities and methadone clinics. Examples of Class B pharmacies include:

(a) closed door;

(b) hospital clinic pharmacy;

(c) methadone clinics;

([~~c~~]d) nuclear;

([~~d~~]e) branch;

([~~e~~]f) hospice facility pharmacy;

([~~f~~]g) veterinarian pharmaceutical facility;

([~~g~~]h) pharmaceutical administration facility; and

([h]i) sterile product preparation facility.

(i) A retail pharmacy that prepares sterile products does not require a separate license as a Class B pharmacy.

(3) Class C pharmacy includes [~~all~~]pharmacies located in Utah that are involved in:

(a) manufacturing;
(b) producing;
(c) wholesaling; and
(d) distributing

(4) Class D pharmacy includes [~~non-resident~~]pharmacies located outside the state of Utah. Class D pharmacies require a pharmacist-in-charge licensed in the state where the pharmacy is located and[~~. Class D pharmacies~~] include[~~:~~

~~(a)~~] Out-of-state mail order pharmacies. Facilities that have multiple locations must have licenses for each facility and every component part of a facility[~~; and~~

~~(b) Out-of-state Internet pharmacies~~].

(5) Class E pharmacy includes those pharmacies that do not require a pharmacist-in-charge and include:

(a) medical gases providers; and

(b) analytical laboratories.

(6) All pharmacy licenses will be converted to the appropriate classification by the Division as identified in Section 58-17b-302.

(7) Each Class A and each Class B pharmacy required to have a pharmacist-in-charge shall have one pharmacist-in-charge who is employed on a full-time basis as defined by the employer, who acts as a pharmacist-in-charge for one pharmacy. However, the pharmacist-in-charge may be the pharmacist-in-charge of more than one Class A pharmacy, if the additional Class A pharmacies are not open to provide pharmacy services simultaneously.

(8) The pharmacist-in-charge shall comply with the provisions of Section R156-17b-603.

R156-17b-304. Licensure - Education Requirements.

(1) In accordance with Subsections 58-17b-303(2) and 58-17b-304(7)(c), the credentialing agency recognized to provide certification and evaluate equivalency of a foreign educated pharmacy graduate is the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy Foundation, or an equivalent credentialing agency as approved by the Division.

(2) In accordance with Subsection 58-17b-304(6), the preliminary education qualification for licensure as a pharmacy intern include:

(a) a current pharmacy student who has completed at least 15 semester hours of pharmacy course work in a college or school of pharmacy accredited by the ACPE;

(b) a graduate who has received a degree from a school or college of pharmacy which is accredited by the ACPE; or

(c) a graduate of a foreign pharmacy school who has received a certificate of equivalency from an approved credentialing agency defined in Subsection (1).

(3) In accordance with Subsection 58-17b-305(1)(f), a pharmacy technician must complete an approved program of education and training that meets the following standards:

(a) The didactic training program must be approved by the Division in collaboration with the Board and must address, at a minimum, the following topics:

(i) legal aspects of pharmacy practice including federal and state laws and rules governing practice;

(ii) hygiene and aseptic techniques;

(iii) terminology, abbreviations and symbols;

(iv) pharmaceutical calculations;

(v) identification of drugs by trade and generic names, and therapeutic classifications;

(vi) filling of orders and prescriptions including packaging and labeling;

(vii) ordering, restocking, and maintaining drug inventory;

(viii) computer applications in the pharmacy; and

(ix) non-prescription products including cough and cold, nutritional, analgesics, allergy, diabetic testing supplies, first aid, ophthalmic, family planning, foot, feminine hygiene, gastrointestinal preparations, and pharmacy care over-the-counter drugs, except those over-the-counter drugs that are prescribed by a practitioner.

(b) This training program's curriculum and a copy of the final examination shall be submitted to the Division for approval by the Board prior to starting any training session with a pharmacy technician in training. The final examination must include questions covering each of the topics listed in Subsection (3)(a) above.

(c) Approval must be granted by the Division in collaboration with the Board before a student may start a program of study. [~~Specific guidelines include:~~

~~(i) an individual currently participating in a program of study that was approved prior to July 1, 2004, must complete the program by April 1, 2005 to be eligible for licensure.~~

~~(ii) a training program that accepts an individual into a program on or after January 1, 2005 must submit a copy of the curriculum no later than November 1, 2004 and have the program approved by the Division in collaboration with the Board.~~

~~(iii) a~~]An individual who completes a non-approved program is not eligible for licensure.

(d) The training program must require at least 180 hours of practical training supervised by a licensed pharmacist in good standing with the Division and must include written protocols and guidelines for the teaching pharmacist outlining the utilization and supervision of pharmacy technicians in training that includes:

(i) the specific manner in which supervision will be completed; and

(ii) an evaluative procedure to verify the accuracy and completeness of all acts, tasks and functions performed by the pharmacy technician in training.

(e) An individual must complete an approved training program and successfully pass the required examinations as listed in Subsection R156-17b-302(3) within one year from the date of the first day of the training program, unless otherwise approved by the Division in collaboration with the Board.

(4) An applicant for licensure as a pharmacy technician is deemed to have met the qualification for licensure in Subsection 58-17b-305(f) if the applicant:

(a) is currently licensed and in good standing in another state and has not had any adverse action taken on that license;

(b) has engaged in the practice as a pharmacy technician for a minimum of 1,000 hours or equivalent experience as approved by the Division in collaboration with the Board; and

(c) has passed and maintained current the PTCB certification or a Board approved equivalent and passed the Utah law exam.

R156-17b-402. Administrative Penalties.

In accordance with Subsection 58-17b-401(6), unless otherwise ordered by the presiding officer, the following fine and citation schedule shall apply.

(1) Preventing or refusing to permit any authorized agent of the Division to conduct an inspection:

initial offense: $500 - $2,000

subsequent offense(s): $5,000

(2) Failing to deliver the license or permit or certificate to the Division upon demand:

initial offense: $100 - $1,000

subsequent offense(s): $500 - $2,000

(3) Using the title pharmacist, druggist, pharmacy intern, pharmacy technician or any other term having a similar meaning or any term having similar meaning when not licensed to do so:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(4) Conducting or transacting business under a name which contains as part of that name the words drugstore, pharmacy, drugs, medicine store, medicines, drug shop, apothecary, prescriptions or any other term having a similar meaning or in any manner advertising otherwise describing or referring to the place of the conducted business or profession when not licensed to do so:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(5) Buying, selling, causing to be sold, or offering for sale any drug or device which bears the inscription sample, not for resale, investigational purposes, or experimental use only or other similar words:

initial offense: $1,000 - $5,000

subsequent offense(s): $10,000

(6) Using to the licensee's own advantage or revealing to anyone other than the Division, Board or its authorized representatives, any information acquired under the authority of this chapter concerning any method or process which is a trade secret:

initial offense: $100 - $500

subsequent offense(s): $200 - $1,000

(7) Illegally procuring or attempting to procure any drug for the licensee or to have someone else procure or attempt to procure a drug:

initial offense: $500 - $2,000

subsequent offense(s): $2,000 - $10,000

(8) Filling, refilling or advertising the filling or refilling of prescription drugs when not licensed do to so:
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000
(9) Requiring any employed pharmacist, pharmacy intern, pharmacy technician or authorized supportive personnel to engage in any conduct in violation of this chapter:
initial offense: $500 - $2,000
subsequent offense(s): $2,500 - $10,000
(10) Being in possession of a drug for an unlawful purpose:
initial offense: $500 - $1,000
subsequent offense(s): $1,500 - $5,000
(11) Dispensing a prescription drug to anyone who does not have a prescription from a practitioner or to anyone who is known or should be known as attempting to obtain drugs by fraud or misrepresentation:
initial offense: $500 - $2,000
subsequent offense(s): $2,500 - $10,000
(12) Selling, dispensing or otherwise trafficking in prescription drugs when not licensed to do so or when not exempted from licensure:
initial offense: $1,000 - $5,000
subsequent offense(s): $10,000
(13) Using a prescription drug or controlled substance for the licensee that was not lawfully prescribed for the licensee by a practitioner:
initial offense: $100 - $500
subsequent offense(s): $1,000 - $2,5000
(14) Willfully deceiving or attempting to deceive the Division, the Board or its authorized agents as to any relevant matter regarding compliance under this chapter:
initial offense: $500 - $2,000
subsequent offense(s): $2,500 - $10,000
(15) Paying rebates to practitioners or any other health care provider, or entering into any agreement with a medical practitioner or any other person for the payment or acceptance of compensation for recommending the professional services of either party:
initial offense: $500 - $2,000
subsequent offense(s): $2,500 - $10,000
(16) Misbranding or adulteration of any drug or device or the sale, distribution or dispensing of any outdated, misbranded, or adulterated drugs or devices:
initial offense: $1,000 - $5,000
subsequent offense(s): $10,000
(17) Accepting back and redistributing any unused drugs, with the exception as provided in Section 58-17b-503:
initial offense: $1,000 - $5,000
subsequent offense(s): $10,000
(18) Violating Federal Title II, PL 91, Controlled Substances Act or Title 58, Chapter 37, Utah Controlled Substances Act, or rules and regulations adopted under either act:
initial offense: $500 - $2,000

subsequent offense(s): $2,500 - $10,000
(19) Failure to follow USP-NF Chapter 797 guidelines:
initial offense: $500 - $2,000
subsequent offense(s) $2,500 - $10,000
(20) Failure to follow USP-NF Chapter 795 guidelines:
initial offense: $250 - $500
subsequent offense(s): $500 - $750
(21) Administering without appropriate guidelines or lawful order:
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000
(22) Disclosing confidential patient information in violation of the provision of the Health Insurance Portability and Accountability Act of 1996 or other applicable law:
initial offense: $100 - $500
subsequent offense(s): $500 - $1,000
(23) Engaging in the practice of pharmacy without a licensed pharmacist designated as the pharmacist in charge:
initial offense: $100 - $500
subsequent offense(s): $2,000 - $10,000
(24) Failing to report to the Division any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency or court:
initial offense: $100 - $500
subsequent offense(s): $500 - $1,000
(25) Compounding a prescription drug for sale to another pharmaceutical facility:
initial offense: $100 - $500
subsequent offense(s): $500 - $1,000
(26) Preparing a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strengths prescribed by a practitioner:
initial offense: $500 - $1,000
subsequent offense(s): $2,500 - $5,000
(27) Violating any ethical code provision of the American Pharmaceutical Association Code of Ethics for Pharmacists, October 27, 1994:
initial offense: $250 - $500
subsequent offense(s): $2,000 - $10,000
([~~29~~]28) Failing to comply with the continuing education requirements set forth in these rules:
initial offense: $100 - $500
subsequent offense(s): $500 - $1,000
(29) Failing to provide the Division with a current mailing address within 10 days following any change of address:
initial offense: $50 - $100
subsequent offense(s): $200 - $300
(30) Defaulting on a student loan:
initial offense: $100 - $200
subsequent offense(s): $200 - $500
(31) Failing to abide by all applicable federal and state law regarding the practice of pharmacy:
initial offense: $500 - $1,000
subsequent offense(s): $2,000 - $10,000

(32) Failing to comply with administrative inspections:
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000
(33) Abandoning a pharmacy and/or leaving drugs accessible to the public:
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000
(34) Failure to return or providing false information on a self-inspection report:
initial offense: $100 - $250
subsequent offense(s): $300 - $500
(35) Failure to pay an administrative fine:
Double the original penalty amount up to $10,000
(36) Any other conduct which constitutes unprofessional or unlawful conduct:
initial offense: $100 - $500
subsequent offense(s): $200 - $1,000[
~~(37) Failure to wear a name tag:~~
~~Individual initial: $50~~
~~Subsequent offense: $100~~
~~Pharmacy any offense: $100 - $200~~]
([~~38~~]37) Failure to maintain an appropriate ratio of personnel:
Pharmacist initial offense: $100 - $250
Pharmacist subsequent offense(s): $500 - $2,500
Pharmacy initial offense: $250 - $1,000
Pharmacy subsequent offense(s): $500 - $5,000
([~~39~~]38) Unauthorized people in the pharmacy:
Pharmacist initial offense: $50 - $100
Pharmacist subsequent offense(s): $250 - $500
Pharmacy initial offense: $250 - $500
Pharmacy subsequent offense(s): $1,000 - $2,000
([~~40~~]39) Failure to offer to counsel:
Pharmacy personnel initial offense: $500 - $2,500
Pharmacy personnel subsequent offense(s): $5,000 - $10,000
Pharmacy: $2,000 per occurrence
([~~41~~]40) Violations of the laws and rules regulating operating standards (security system, unkempt facility, no hot water, etc.) in a pharmacy discovered upon inspection by the Division:
initial violation: $50 - $100
failure to comply within determined time: $250 - $500
subsequent violations: $250 - $500
failure to comply within established time: $750 - $1,000
([~~42~~]41) Practicing or attempting to practice as a pharmacist, pharmacist intern, or pharmacy technician or operating a pharmacy without a license:
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000
([~~43~~]42) Impersonating a licensee or practicing under a false name:
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000
([~~44~~]43) Knowingly employing an unlicensed person:

initial offense: $500 - $1,000
subsequent offense(s): $1,000 - $5,000

([~~45~~]44) Knowingly permitting the use of a license by another person:
initial offense: $500 - $1,000
subsequent offense(s): $1,000 - $5,000

([~~46~~]45) Obtaining a passing score, applying for or obtaining a license or otherwise dealing with the Division or Board through the use of fraud, forgery, intentional deception, misrepresentation, misstatement, or omission:
initial offense: $100 - $2,000
subsequent offense(s): $2,000 - $10,000

([~~47~~]46) Violating or aiding or abetting any other person to violate any statute, rule or order regulating pharmacy:
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000

([~~48~~]47) Violating or aiding or abetting any other person to violate any generally accepted professional or ethical standard:
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000

([~~49~~]48) Engaging in conduct that results in conviction of, or a plea of nolo contendere, or a plea of guilty or nolo contendere held in abeyance to a crime:
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000

([~~50~~]49) Engaging in conduct that results in disciplinary action by any other jurisdiction or regulatory authority:
initial offense: $100 - $500
subsequent offense(s): $200 - $1,000

([~~51~~]50) Engaging in conduct, including the use of intoxicants or drugs, to the extent that the conduct does or may impair the ability to safely engage in practice as a pharmacist, pharmacy intern or pharmacy technician:
initial offense: $100 - $500
subsequent offense(s): $200 - $1,000

([~~52~~]51) Practicing or attempting to practice as a pharmacist, pharmacy intern or pharmacy technician when physically or mentally unfit to do so:
initial offense: $100 - $500
subsequent offense(s): $200 - $1,000

([~~53~~]52) Practicing or attempting to practice as a pharmacist, pharmacy intern, or pharmacy technician through gross incompetence, gross negligence or a pattern of incompetency or negligence:
initial offense: $500 - $2,000
subsequent offense(s): $2,000 - $10,000

([~~54~~]53) Practicing or attempting to practice as a pharmacist, pharmacy intern or pharmacy technician by any form of action or communication which is false, misleading, deceptive or fraudulent:
initial offense: $100 - $500
subsequent offense(s): $200 - $1,000

([~~55~~]54) Practicing or attempting to practice as a pharmacist, pharmacy intern or pharmacy technician beyond the individual's scope of competency, abilities or education:
initial offense: $100 - $500
subsequent offense(s): $200 - $1,000
([~~56~~]55) Practicing or attempting to practice as a pharmacist, pharmacy intern or pharmacy technician beyond the scope of licensure:
initial offense: $100 - $500
subsequent offense(s): $200 - $1,000
([~~57~~]56) Verbally, physically or mentally abusing or exploiting any person through conduct connected with the licensee's practice:
initial offense: $100 - $1,000
subsequent offense(s): $500 - $2,000
([~~58~~]57) Failure to comply with the pharmacist-in-charge standards:
initial offense: $500 - $2,000
subsequent offense(s) $2,000 - $10,000
([~~59~~]58) Failure to resolve identified drug therapy management problems:
initial offense: $500 - $2,500
subsequent offense: $5,000 - $10,000

R156-17b-605. Operating Standards - Inventory Requirements.
(1) General requirements for inventory of a pharmacy shall include the following:
(a) the pharmacist-in-charge shall be responsible for taking all required inventories, but may delegate the performance of the inventory to another person or persons;
(b) the inventory records must be maintained for a period of five years and be readily available for inspection;
(c) the inventory records shall be filed separately from all other records;
(d) the inventory records shall be in a typewritten or printed form and include all stocks of legend drugs and controlled substances on hand on the date of the inventory including any that are out of date drugs and drugs in automated pharmacy systems. An inventory taken by use of a verbal recording device must be promptly transcribed;
(e) the inventory may be taken either as of the opening of the business or the close of business on the inventory date;
(f) the person taking the inventory and the pharmacist-in-charge shall indicate the time the inventory was taken and shall sign and date the inventory with the date the inventory was taken. The signature of the pharmacist-in-charge and the date of the inventory shall be documented within 72 hours or three working days of the completed initial, annual, change of ownership and closing inventory;
(g) the person taking the inventory shall make an exact count or measure all controlled substances listed in Schedule I or II;
(h) the person taking the inventory shall make an estimated [~~court~~]count or measure all Schedule III, IV or V controlled

substances and legend drugs, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents must be made;

(i) the inventory of Schedule I and II controlled substances shall be listed separately from the inventory of Schedule III, IV and V controlled substances which shall be listed separately from the inventory of the legend drugs; and

(j) if the pharmacy maintains a perpetual inventory of any of the drugs required to be inventoried, the perpetual inventory shall be reconciled on the date of the inventory.

(2) Requirement for taking the initial inventory shall include the following:

(a) all pharmacies having any stock of legend drugs or controlled substances shall take an inventory on the opening day of business. Such inventory shall include all stock of legend drugs and controlled substances including any out-of-date drugs and drugs in automated pharmacy systems;

(b) in the event a pharmacy commences business with none of the drugs specified in paragraph (2)(a) of this section on hand, the pharmacy shall record this fact as the initial inventory; and

(c) the initial inventory shall serve as the pharmacy's inventory until the next completed inventory as specified in Subsection (3) of this section.

(3) Requirement for annual inventory shall be 12 months following the inventory date of each year and may be taken within four days of the specified inventory date and shall include all stocks including out-of-date drugs and drugs in automated pharmacy systems.

(4) Requirements for change of ownership shall include the following:

(a) a pharmacy that changes ownership shall take an inventory of all legend drugs and controlled substances including out-of-date drugs and drugs in automated pharmacy systems on the date of the change of ownership;

(b) such inventory shall constitute, for the purpose of this section, the closing inventory for the seller and the initial inventory for the buyer; and

(c) transfer of Schedule I and II controlled substances shall require the use of official DEA order forms (Form 222).

(5) Requirement for taking inventory when closing a pharmacy includes the pharmacist-in-charge, owner, or the legal representative of a pharmacy that ceases to operate as a pharmacy shall forward to the Division, within ten days of cessation of operation, a statement attesting that an inventory has been conducted, the date of closing and a statement attesting the manner by which legend drugs and controlled substances possessed by the pharmacy were transferred or disposed.

(6) Requirements specific to taking inventory in a Class B pharmacy shall include the following:

(a) all Class B pharmacies shall maintain a perpetual inventory of all Schedule II controlled substances which shall be reconciled according to facility policy; and

(b) the inventory of the institution shall be maintained in the pharmacy; if an inventory is conducted in other departments

within the institution, the inventory shall be listed separately as follows:

(i) the inventory of drugs on hand in the pharmacy shall be listed separately from the inventory of drugs on hand in the other areas of the institution; and

(ii) the inventory of the drugs on hand in all other departments shall be identified by department.

R156-17b-609. Operating Standards - Medication Profile System.

In accordance with Subsections 58-17b-601(1) and 58-17b-604(1), the following operating standards shall apply with respect to medication profile systems:

(1) Patient profiles, once established, shall be maintained by a pharmacist in a pharmacy dispensing to patients on a recurring basis for a minimum of one year from the date of the most recent prescription filled or refilled; except that a hospital pharmacy may delete the patient profile for an inpatient upon discharge if a record of prescriptions is maintained as a part of the hospital record.

(2) Information to be included in the profile shall be determined by a responsible pharmacist at the pharmaceutical facility but shall include as a minimum:

(a) full name of the patient, address, telephone number, date of birth or age and gender;

(b) patient history where significant, including known allergies and drug reactions, and [~~a list of medications and relevant devices obtained at the pharmacy;~~

~~(c)~~]a list of prescription drugs obtained by the patient at the pharmacy including:

(i) name of prescription drug;

(ii) strength of prescription drug;

(iii) quantity dispensed;

(iv) date of filling or refilling;

(v) charge for the prescription drug as dispensed to the patient; and

([~~d~~]c) any additional comments relevant to the patient's drug use.

(3) Patient medication profile information shall be recorded by a pharmacist, pharmacy intern or pharmacy technician.

R156-17b-612. Operating Standards - Prescriptions.

In accordance with Subsection 58-17b-601(1), the following shall apply to prescriptions:

(1) Prescription order shall be handled according to the rules of the Federal Drug Enforcement Administration.

(2) A prescription issued by an authorized licensed practitioner, if verbally communicated by an agent of that practitioner upon that practitioner's specific instruction and authorization, may be accepted by a pharmacist or pharmacy intern.

(3) A prescription issued by a licensed prescribing practitioner, if electronically communicated by an agent of that practitioner, upon that practitioner's specific instruction and

authorization, may be accepted by a pharmacist, pharmacy intern and pharmacy technician.

(4) In accordance with Section 58-17b-609, prescription files, including refill information, shall be maintained for a minimum of five years [~~by either a manual filing of written prescriptions or by an~~]and shall be immediately retrievable in written or electronic [~~record~~]format.

(5) Prescriptions having a remaining authorization for refill may be transferred by the pharmacist at the pharmacy holding the prescription to a pharmacist at another pharmacy upon the authorization of the patient to whom the prescription was issued. The transferring pharmacist and receiving pharmacist shall act diligently to ensure that the total number of authorized refills is not exceeded.

(6) Prescriptions for terminal patients in licensed hospices, home health agencies or nursing homes may be partially filled if the patient has a medical diagnosis documenting a terminal illness and may not need the full prescription amount.

(7) Refills may be dispensed only in accordance with the prescriber's authorization as indicated on the original prescription drug order;

(8) If there are no refill instructions on the original prescription drug order, or if all refills authorized on the original prescription drug order have been dispensed, authorization from the prescribing practitioner must be obtained prior to dispensing any refills.

(9) Refills of prescription drug orders for legend drugs may not be refilled after one year from the date of issuance of the original prescription drug order without obtaining authorization from the prescribing practitioner prior to dispensing any additional quantities of the drug.

(10) Refills of prescription drug orders for controlled substances shall be done in accordance with Subsection 58-37-6(7)(f).

(11) A pharmacist may exercise his professional judgment in refilling a prescription drug order for a drug, other than a controlled substance listed in Schedule II, without the authorization of the prescribing practitioner, provided:

(a) failure to refill the prescription might result in an interruption of a therapeutic regimen or create patient suffering;

(b) either:

(i) a natural or manmade disaster has occurred which prohibits the pharmacist from being able to contact the practitioner; or

(ii) the pharmacist is unable to contact the practitioner after a reasonable effort, the effort should be documented and said documentation should be available to the Division;

(c) the quantity of prescription drug dispensed does not exceed a 72-hour supply, unless the packaging is in a greater quantity;

(d) the pharmacist informs the patient or the patient's agent at the time of dispensing that the refill is being provided

without such authorization and that authorization of the practitioner is required for future refills;

(e) the pharmacist informs the practitioner of the emergency refill at the earliest reasonable time;

(f) the pharmacist maintains a record of the emergency refill containing the information required to be maintained on a prescription as specified in this subsection; and

(g) the pharmacist affixes a label to the dispensing container as specified in Section 58-17b-602.

(12) If the prescription was originally filled at another pharmacy, the pharmacist may exercise his professional judgment in refilling the prescription provided:

(a) the patient has the prescription container label, receipt or other documentation from the other pharmacy which contains the essential information;

(b) after a reasonable effort, the pharmacist is unable to contact the other pharmacy to transfer the remaining prescription refills or there are no refills remaining on the prescription;

(c) the pharmacist, in his professional judgment, determines that such a request for an emergency refill is appropriate and meets the requirements of (a) and (b) of this subsection; and

(d) the pharmacist complies with the requirements of Subsections (11)(c) through (g) of this section.

(13) The transfer of original prescription drug order information for legend drugs and Schedule III through V controlled substances is permissible between pharmacies on a one time basis, except transfers back to the pharmacy making the original transfer and transfers within the same corporate pharmacy chain with a computer pharmacy system which accounts for the transfer to all sites, only for the valid remaining refills except as described in Subsection R156-17b-613(9).

(a) the transfer shall be communicated directly between pharmacists or pharmacy interns or as authorized under Subsection R156-17b-613(9):

(b) both the original and the transferred prescription drug orders shall be maintained for a period of five years from the date of the last refill;

(c) the pharmacist or pharmacy intern transferring the prescription drug order shall void the prescription electronically or write void on the face of the invalidated prescription manually;

(d) the pharmacist or pharmacy intern receiving the transferred prescription drug order shall:

(i) indicate on the prescription record that the prescription was transferred electronically or manually; and

(ii) record on the transferred prescription drug order the following information:

(A) original date of issuance and date of dispensing or receipt, if different from date of issuance;

(B) original prescription number and the number of refills authorized on the original prescription drug order;

(C) number of valid refills remaining and the date of last refill, if applicable;

(D) the name, address and, if a controlled substance, the DEA registration number of the pharmacy to which such prescription is transferred; and

(E) the name of the pharmacist or pharmacy intern transferring the prescription drug order information;

(e) the data processing system shall have a mechanism to prohibit the transfer or refilling of legend or controlled substance prescription drug orders which have been previously transferred; and

(f) a pharmacist or pharmacy intern may not refuse to transfer original prescription information to another pharmacist or pharmacy intern who is acting on behalf of a patient and who is making a request for this information as specified in Subsections (12) and (13) of this section.

R156-17b-616. Operating Standards - Class D Pharmacy - [~~Non-Residence~~]Out of State Mail Order Pharmacies.

(1) In accordance with Subsections 58-1-301(3) and 58-17b-306(2), an application for licensure as a Class D pharmacy shall include:

(a) a pharmacy care protocol that includes the operating standards established in Subsections R156-17b-610(1) and (8) and R156-17b-614(1) through (4);

(b) a copy of the pharmacist's license for the pharmacist-in-charge; and

(c) a copy of the most recent state inspection showing the status of compliance with the laws and regulations for physical facility, records and operations.

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